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July 31, 2009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Paul J. Carter and Hongxing Zhou

Serial No.: 10/578,410 Group Art Unit No.: 1644

Filed: March 5, 2007 Examiner: SKELDING, Zachary S.

For: ANTIBODIES THAT BIND INTERLEUKIN-4 RECEPTOR

Docket No.: 3492-US-PCT

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

Applicants respectfully request reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced application for the following reasons.

Petition under *Wyeth v. Dudas*

"A Delays" are defined by 35 U.S.C. § 154(b)(1)(A) as delays in prosecution by The Office that can result in the accumulation of Patent Term Adjustment for a patent issuing from the delayed application. "B Delays" are defined by 35 U.S.C. § 154(b)(1)(B) for application pendencies exceeding three years. However, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A).

Wyeth et al. v. Jon W. Dudas (U.S. District Court, D.C., CA No. 07-1492, Mem. Op. September 30, 2008) holds that the "A Delay" and "B Delay" periods for an application overlap only if they occur on the same day(s). To the extent that the "A Delay" for an application occurs on different days than its "B Delay," the two delays do not overlap.

The Determination of Patent Term Adjustment issued in connection with the above-referenced application, and the recordation of Patent Term Adjustment found on its private PAIR

CERTIFICATE OF EFS-Web TRANSMISSION
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Jae Cho — July 31, 2009
Date

website, appears to rely on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) before the initial three-year period expired, in violation of the holding of Wyeth v. Dudas. Thus, Applicants respectfully request that the total period of Patent Term Adjustment be recalculated consistent with the holding of Wyeth v. Dudas.

Measuring "B Delay" for a National Stage Filing under 35 U.S.C. § 371

In addition to, and independent of, the "overlap" issue addressed in the Wyeth v. Dudas decision, Applicants respectfully submit that The Office did not apply the proper standard for determining the period of "B Delay" under 35 U.S.C. § 154(b)(1)(B). It is Applicants' understanding that for purposes of calculating "B Delay," The Office measured application pendency as beginning on March 5, 2007, the date on which the application fulfilled the requirements of 35 U.S.C. § 371. However, as detailed below, the relevant statutes and regulations require that when calculating "B Delay" for a national stage filling under 35 U.S.C. § 371, application pendency must be measured from the date that is 30 months from the priority date of the international application (not from the date on which the application fulfilled the requirements of 35 U.S.C. § 371), *i.e.*, on May 7, 2006.

The term of a patent shall, under certain circumstances, be extended if the Office fails to issue a patent within three years after the "actual filing date" of the application.

> (B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY. – Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States…the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued. 35 U.S.C. § 154(b)(1)(B). (emphasis added)

35 U.S.C. § 1.702(b) explains the meaning of the term "actual filing date" as used in 35 U.S.C. § 154(b)(1)(B). As detailed below, PTO delay for a national stage application begins if the Office fails to issue a patent within three years after the date of the national stage "commenced under 35 U.S.C. § 371(b) or (f)."[1]

[1] Consistent with 35 U.S.C. § 1.702(b), MPEP § 2730 states that "[i]n the case of an international application, the phrase 'actual filing date of the application in the United States' [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stage commenced under 35 U.S.C. § 371(b) or (f)."

> (b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to provisions of 35 U.S.C. § 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. § 111(a) or the national stage commenced under 35 U.S.C. § 371(b) or (f) in an international application, but not including... 35 U.S.C. § 1.702(b). (emphasis added)

35 U.S.C. § 371(b) and (f) refer to the time when a national stage application "commences."

> (b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. 35 U.S.C. § 371(b). (emphasis added)
> (f) At the express request of the applicant, the national stage processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with. 35 U.S.C. § 371(f).

35 U.S.C. § 371(f) relates to the situation where an applicant files an express request for early processing of an international application. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), *i.e.*, with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The term "the treaty" refers to "the Patent Cooperation Treaty done at Washington, on June 19, 1970." See 35 U.S.C. § 351(a).

The articles of the Patent Cooperation Treaty cited in 35 U.S.C. § 371(b) are reproduced below.

> **Article 22**
> **Copy, Translation, and Fee to Designated Offices**
> (1) The applicant shall furnish a copy of the international application (unless the communication provided for in Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each designated Office not later than at the expiration of 30 months from the priority date. Where the national law of the designated State requires the indication of the name of and other prescribed data concerning the inventor but allows that these indications be furnished at a time later than that of the filing of a national application, the applicant shall, unless they were contained in the request, furnish the said indications to the national Office of or acting for the State not later than at the expiration of 30 months from the priority date. (emphasis added)

(2) Where the International Searching Authority makes a declaration, under Article 17(2)(a), that no international search report will be established, the time limit for performing the acts referred to in paragraph (1) of this Article shall be the same as that provided for in paragraph (1).

Article 39
Copy, Translation, and Fee, to Elected Offices

(1) (a) If the election of any Contracting State has been effected prior to the expiration of the 19th month from the priority date, the provisions of Article 22 shall not apply to such State and the applicant shall furnish a copy of the international application (unless the communication under Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each elected Office not later than at the expiration of 30 months from the priority date. (emphasis added)

"The applicable time limit" referred to in Patent Cooperation Treaty articles 22(1), 22(2), and 39(1)(a) is "the expiration of 30 months from priority date." As a result, "the expiration of 30 months from the priority date" is the time at which the U.S. national stage commences under provisions of 35 U.S.C. § 371(b). This same conclusion as to the timing for commencement of the U.S. national stage is also summarized in MPEP § 1893.01.

Subject to 35 U.S.C. 371(f), commencement of the national stage occurs upon expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1)(a). See 35 U.S.C. 371(b) and 37 CFR 1.491(a). PCT Articles 22(1), 22(2), and 39(1)(a) provide for a time limit of not later than the expiration of 30 months from the priority date. Thus, in the absence of an express request for early processing of an international application under 35 U.S.C. 371(f) and compliance with the conditions provided therein, the U.S. national stage will commence upon expiration of 30 months from the priority date of the international application. Pursuant to 35 U.S.C. 371(f), the national stage may commence earlier than 30 months from the priority date, provided applicant makes an express request for early processing and has complied with the applicable requirements under 35 U.S.C. 371(c). MPEP § 1893.01. (emphasis added)

In view of the forgoing, the "actual filing date" of a U.S. national stage application filed under 35 U.S.C. § 371, for purposes of calculating "B Delay" under 35 U.S.C. § 154(b)(1)(B) and 35 U.S.C. § 1.702(b), is the date that is 30 months from the priority date of the international application[2].

[2] In contrast to reliance on "the expiration of 30 months from the priority date" for measuring "B Delay," the beginning of the relevant period for purposes of calculating "A Delay" is the date on which an international application fulfills the requirements of 35 U.S.C. § 371. See 35 U.S.C. § 154(b)(1)(A)(i)(II) and 35 U.S.C. § 1.702(a)(1).

"B Delay"

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/US2004/37242, filed November 4, 2004, which claims the benefit of U.S. Provisional application number 60/518,166, filed November 7, 2003.

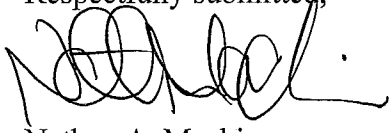
The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371(b), *i.e.*, upon expiration of 30 months from the priority date of the international application.[3] As a result, the date that the national stage commenced was May 7, 2006 (*i.e.*, 30 months from the priority date of November 7, 2003).

Applicants respectfully request that the Patent Term Adjustment for the above-referenced application be determined in light of the foregoing.

Please charge Deposit Account 09-0089 in the name of Immunex Corporation the amount of $200, the fee prescribed by 37 CFR 1.18(e).

The Commissioner is hereby authorized to charge any additional fees which may be required by the accompanying papers, or credit any overpayment to Deposit Account No. 09-0089.

Respectfully submitted,



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[3] No request for early processing under 35 U.S.C. § 371(f) was filed for present application.